REMARKS

Claims 53-55, 57-63, 66-69, and 71-76 were under consideration in the instant application. Claims 53, 55 and 66-76 were amended to correct claim dependencies, typographical errors, and other informalities. Claims 29-31, 35-37, 43-48, 52, 56, 64, 65, 70, and 77-87 have been cancelled without prejudice as being drawn to non-elected inventions. Accordingly, after entry of the instant amendments, claims 53-55, 57-63, 66-69, and 71-76 will be pending in the application. No new matter has been added by way of the amendments. Support for the amendments can be found in the specification and claims as originally filed, and the instant claims as originally presented. Applicants submit herewith a "VERSION WITH MARKINGS TO SHOW CHANGES MADE", which indicates the specific amendments made to the claims. For Examiner's convenience, all of the claims that will be pending in the application upon entry of the amendments presented herein, whether or not amended, are attached hereto as Appendix A. Applicants reserve the right to pursue the subject matter of the cancelled claims in this or a separate application.

Applicants wish to thank the Examiner for the courtesy of a telephone interview on May 20, 2002.

Claim Objections

Claims 63 and 76 have been objected to because they are substantial duplicates of each other. Applicants have amended 76 to depend from claim 74. In light of this amendment, Applicants submit that claim 76 is not a substantial duplicate of claim 63 and respectfully request reconsideration and withdrawal of the objection.

Claims 69 and 71-72 have been objected to because the recitation of "The complex of claim 66" in dependent claims 69 and 71-72 is inconsistent with the recitation of "The MHC complex of claim 66" as recited in dependent claim 67. Applicants have amended claims 69 and 71-72 to recite "The MHC complex of claim 66". In light of this amendment, Applicants submit that the claims are consistent and respectfully request reconsideration and withdrawal of the objection to claims 69 and 71-72.

Rejection of claims 53-55, 57-63, 66-69, and 71-76 under 35 U.S.C. § 112, first paragraph

The rejection of claims 53-55, 57-63, 66-69 and 71-76 under 35 U.S.C. 112, first paragraph has been maintained. According to the Examiner,

> [t]here is no support in the specification or claims as originally filed for the recitation of a single chain class II molecule or a single chain MHC class II-peptide complex comprising a class II beta chain and a class II alpha chain, wherein one r both of said chains are "truncated compared to the full length chain". There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter**. (*Emphasis in original.*)

The Examiner concedes that the peptide binding groove, the multivalent MHC molecules, tagged molecules, and truncated molecules are each supported in the specification. However, in support of the rejection, the Examiner contends that the specification does "not appear to support the limitation of the truncated molecules when presented in the full context of the claims, which also include the limitation of lacking a functional transmembrane domain. It is noted that a non-functional domain can be created by substitution as well as by deletion of amino acids."

Applicants respectfully traverse this rejection and maintain the position that the pending application fully satisfies the requirements of §112, including the written description requirements of § 112, first paragraph.

To satisfy the written description requirement, a patent specification must describe the claimed invention in such detail that one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed Cir 1991).

As noted previously by Applicants and acknowledged by the Examiner, the truncated MHC molecules of the instant invention are described on pages 23-24 of the specification. The specification further discloses at page 7, lines 1-4, that "[s]ingle chain MHC peptide fusion

molecules of the present invention ... may be truncated (particularly, not including a transmembrane portion), or may be 'full-length' and include a transmembrane portion".

As indicated by the above-quoted passage, the limitation of truncated molecules was clearly intended to cover any and all of the MHC molecules disclosed in the specification, including the pending claims. Applicants submit that one of skill in the art would therefore conclude that Applicants had possession of the claimed invention at the time of filing. Accordingly, Applicants submit that there was adequate written description of the claimed invention in the instant specification, and therefore the pending claims are not new matter.

However, in the interest of expediting prosecution, and in no way conceding to the validity of the rejection, Applicants have amended independent claims 53 and 66 to remove the word "functional", so that the claims now recite the phrase "lack a transmembrane domain". Applicants submit that this phrase is fully supported by the specification, as detailed above.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 53-55, 57-63, 66-69 and 71-76 under 35 U.S.C. 112, first paragraph.

Rejection of claims 66-69 and 71-76 under 35 U.S.C. § 112, second paragraph

Claims 66-69 and 71-76 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite "in their recitation of the phrase a single chain MHC Class-II peptide, as recited in lines 1-2 of claim 66 and dependent claims 67-69 and 71-76, because it is not clear what is meant by said phrase." At the suggestion of the Examiner, the word --complex-- has been inserted between the word "peptide" and the word "comprising" in line 1 of claim 66, which was the recitation before the amendment filed 9-16-02. In view of the foregoing, Applicants submit that the claims are definite and respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

CONCLUSION

It is believed the application is in condition for immediate allowance, which action is earnestly solicited. If a telephone conversation with Applicants' agent would expedite the prosecution of the above-identified application, the examiner is urged to call the undersigned at (617) 439-4444.

Respectfully submitted,

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Date: **May 23, 2003**

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 53, 55, 66-69, and 71-76 have been amended as follows:

53. **(Amended)** A single chain class II MHC molecule comprising:

a peptide-binding groove and

covalently linked in sequence: 1) a class II β chain, 2) a single chain linker, and 3) a class II α chain,

wherein the chain of 1) or 3) or both 1) and 3) lack a ~~functional~~ transmembrane domain and

the chain of 1) or 3) or both 1) and 3) are truncated compared to its respective full length chain.

55. **(Amended)** The MHC molecule of claim 53, wherein the chain of 1) comprises a β1 domain and the chain of 3) comprises an α1 domain.

66. **(Amended)** A single chain MHC class II-peptide complex comprising:

a peptide-binding groove;

covalently linked in sequence: 1) a class II β chain, 2) a single chain linker, and 3) a class II α chain, wherein the chain of 1) or 3) or both 1) and 3) lack a ~~functional~~ transmembrane domain and the chain of 1) or 3) or both 1) and 3) are truncated compared to its respective full length chain; and

a presenting peptide being covalently linked to the MHC molecule.

67. **(Amended)** The MHC complex of claim ~~65~~ 66, wherein the complex is soluble.

68. **(Amended)** The MHC ~~molecule~~ complex of claim ~~65~~ 66, wherein the chains of 1) and 3) comprise a β1 domain and α1 domain, respectively.

69. **(Amended)** The MHC complex of claim ~~65~~ 66, wherein the MHC class II molecule comprises the presenting peptide covalently linked to the β chain.

71. **(Amended)** The MHC complex of claim ~~65~~ 66, wherein a presenting peptide linker sequence is interposed between the presenting peptide and the MHC molecule.

72. **(Amended)** The MHC complex of claim ~~65~~ 66, wherein the β and α chains are each independently selected from the group consisting of IE, IA, DR, DQ and DP proteins.

73. **(Amended)** The MHC ~~molecule~~ complex of claim ~~65~~ 66, wherein the MHC molecule is modified to carry a detectable tag.

74. **(Amended)** A multivalent MHC complex comprising two or more linked MHC molecules of claim ~~65~~ 66.

75. **(Amended)** The MHC complex of claim ~~73~~ 74, wherein the MHC molecules are linked to immunoglobulin domains.

76. **(Amended)** The MHC complex of claim ~~60~~ 74, wherein the MHC complex is modified to carry a detectable tag.

APPENDIX A

53. A single chain class II MHC molecule comprising:

a peptide-binding groove and

covalently linked in sequence: 1) a class II β chain, 2) a single chain linker, and 3) a class II α chain,

wherein the chain of 1) or 3) or both 1) and 3) lack a transmembrane domain and

the chain of 1) or 3) or both 1) and 3) are truncated compared to its respective full length chain.

54. The MHC molecule of claim 53, wherein the MHC molecule is soluble.

55. The MHC molecule of claim 53, wherein the chain of 1) comprises a β1 domain and the chain of 3) comprises an α1 domain.

57. The MHC molecule of claim 53, wherein the single chain linker is linked between the carboxyl terminus of the β chain and the amino terminus of the α chain.

58. The MHC molecule of claim 53, wherein the β and α chains are each independently selected from the group consisting of IE, IA, DR, DQ and DP proteins.

59. The MHC molecule of claim 53 further comprising a presenting peptide non-covalently linked to a peptide binding groove of the MHC molecule.

60. The MHC molecule of claim 53 wherein the MHC molecule is modified to carry a detectable tag.

61. A multivalent MHC complex comprising two or more linked MHC molecules of claim 53.

SWD

62. A MHC complex of claim 61 wherein the MHC molecules are linked to immunoglobulin domains.

63. A MHC complex of claim 61 wherein the MHC complex is modified to carry a detectable tag.

66. A single chain MHC class II-peptide complex comprising:

SWD

a peptide-binding groove;

covalently linked in sequence: 1) a class II β chain, 2) a single chain linker, and 3) a class II α chain, wherein the chain of 1) or 3) or both 1) and 3) lack a transmembrane domain and the chain of 1) or 3) or both 1) and 3) are truncated compared to its respective full length chain; and

a presenting peptide being covalently linked to the MHC molecule.

SWD

67. The MHC complex of claim 66, wherein the complex is soluble.

SWD

68. The MHC complex of claim 66, wherein the chains of 1) and 3) comprise a β1 domain and α1 domain, respectively.

SWD

69. The MHC complex of claim 66, wherein the MHC class II molecule comprises the presenting peptide covalently linked to the β chain.

SWD

71. The MHC complex of claim 66, wherein a presenting peptide linker sequence is interposed between the presenting peptide and the MHC molecule.

SWD

72. The MHC complex of claim 66, wherein the β and α chains are each independently selected from the group consisting of IE, IA, DR, DQ and DP proteins.

73. The MHC complex of claim 66, wherein the MHC molecule is modified to carry a detectable tag.

74. A multivalent MHC complex comprising two or more linked MHC molecules of claim 66.

75. The MHC complex of claim 74, wherein the MHC molecules are linked to immunoglobulin domains.

76. The MHC complex of claim 74, wherein the MHC complex is modified to carry a detectable tag.